510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE TEMPLATE

A. 510(k) Number: K031856

B. Analyte: Preciset TDM I and TDM II Calibrators

C. Type of Test: N/A

D. Applicant: Roche Diagnostics

E. Proprietary and Established Names: Preciset TDM I and TDM II Calibrators

F. Regulatory Information:

1. Regulation section: 21 CFR 862.3200

2. Classification: Class II

3. Product Code: DKB

4. Panel: 91

G. Intended Use:

1. Indication(s) for use: The Roche Preciset TDM I calibrators are designed for the calibration of the Roche assay for the quantitative determination of digoxin, carbamazepine, gentamicin, phenytoin, phenobarbital, primidone, theophylline, tobramycin, valproic acid, and vancomycin in human serum and plasma on automated clinical chemistry analyzers.

2. The Roche Preciset TDM II calibrators are designed for the calibration of the Roche assay for the quantitative determination of digitoxin, amikacin, lidocaine, N-acetylprocainamide, procainamide, and quinidine in human serum and plasma on automated clinical chemistry analyzers.

3. Special condition for use statement(s): none

4. Special instrument Requirements: none

H. Device Description: The Roche Preciset TDM I calibrators are designed for the calibration of the Roche assay for the quantitative determination of digoxin, carbamazepine, gentamicin, phenytoin, Phenobarbital, primidone, Theophylline, tobramycin, valproic acid, and vancomycin in human serum and plasma on automated

clinical chemistry analyzers. The Roche Preciset TDM II calibrators are designed for the calibration of the Roche assay for the quantitative determination of digoxin, amikacin, lidocaine, N-acetylprocainamide, procainamide, and quinidine in human serum and plasma on automated clinical chemistry analyzers. These calibrators are liquid ready to use calibrators consisting of six levels, and a drug free diluent.

I. Substantial Equivalence Information:

Predicate device name(s): **TDM I** -Roche COBAS-FP Reagents and Calibrators for Digoxin - K851032, Carbamazepine – K850807, Gentamicin – K843827 & K945523, Phenytoin – K936131, Phenobarbital – K936130, Primidone – K852318, Theophylline – K871484, Tobramycin – K843828, Valproic Acid – K925003, and Vancomycin – K901759 **TDM II** COBAS INTEGRA, Calibrators & Controls – K972250, Roche COBAS-FP Reagents and Calibrators for Amikacin – 852317, Lidocaine – K853010, NAPA – K871680, Procainamide – K852320 & K942847/S2 and Quinidine – K941440

Predicate K number(s): **TDM I** -Roche COBAS-FP Reagents and Calibrators for Digoxin - K851032, Carbamazepine – K850807, Gentamicin – K843827 & K945523, Phenytoin – K936131, Phenobarbital – K936130, Primidone – K852318, Theophylline – K871484, Tobramycin – K843828, Valproic Acid – K925003, and Vancomycin – K901759 **TDM II** COBAS INTEGRA, Calibrators & Controls – K972250, Roche COBAS-FP Reagents and Calibrators for Amikacin – 852317, Lidocaine – K853010, NAPA – K871680, Procainamide – K852320 & K942847/S2 and Quinidine – K941440

3. Comparison with predicate:

DEVICE	PREDICATE
A. Similarities	
Liquid ready to use calibrators, 6 levels, bottles A-F Human Serum with stabilizer and preservative.	Liquid ready to use calibrators, 6 levels, bottles A-F Human Serum with stabilizer and preservative.
B. Differences	
The Roche Preciset TDM I calibrators are designed for the calibration of the Roche assay for the quantitative determination of digoxin, carbamazepine, gentamicin, phenytoin, Phenobarbital, primidone, Theophylline, tobramycin, valproic acid, and vancomycin in human serum and plasma on automated clinical chemistry analyzers. The Roche Preciset TDM II calibrators are designed for the	The predicates (listed in Section H) consisted of individual calibrators for each test.

calibration of the Roche assay for the quantitative determination of digoxin, amikacin, lidocaine, N-acetylprocainamide, procainamide, and quinidine in human serum and plasma on automated clinical chemistry analyzers.	

J. Standard/Guidance Document Referenced (if applicable) Guidance for Industry - Abbreviated 510(k) Submissions for InVitro Calibrators

K. Test Principle: N/A

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility: N/A

   b. Linearity/assay reportable range: N/A

   c. Traceability (controls, calibrators, or method): traceable to single analyte primary master calibrators prepared gravimetrically and by dilution from pure drugs of the highest metrological order

   d. Detection limit (functional sensitivity: N/A

   e. Analytical specificity: N/A

   f. Assay cut-off: N/A

2. Comparison studies:
   a. Method comparison with predicate device: N/A

   b. Matrix comparison: N/A

3. Clinical studies:
   a. Clinical sensitivity: N/A

   b. Clinical specificity: N/A

4. Clinical cut-off: N/A

5. Expected values/Reference range: N/A

M. Conclusion:

Based upon the information provided, I recommend that the Roche Preciset TDM I and II multianalyte calibrators be found substantially equivalent with similar defined products based upon 21 CFR 862.3200.